

REMARKS

The Applicant requests that the above Amendment be entered and the application examined as amended and in view of the remarks below.

By this Amendment the Applicant introduced a “Cross Reference to Related Applications” and amended numerous claims to more precisely recite aspects of the invention. No claims were amended to overcome prior art.

In addition, the applicant introduced new claims 56 and 57. Support for new claims 56 and 57 are found in prior claim 35.

Claims 35, 36, 38-43, 45-47, 49, and 51 through 57 are now pending in this application.

I Response to Obviousness Rejection Based upon Hayhurst and Fallin

In paragraphs 4, 5, and 6 on pages 3 and 4 of the Action, the Patent Office rejected claims 35, 36, 38, 43, 45-47, 49, 54, and 55 pursuant to 35 U.S.C. §103(a) as obvious in view of the combined teachings of U.S. Patent 5,647,874 of Hayhurst [herein “Hayhurst”] and U.S. Patent 6,9782,027 of Fallin, et al. [herein “Fallin”]. The Applicant respectfully submits that these rejections are inappropriate and requests that these rejections be reconsidered and withdrawn based upon the following comments and observations.

IA Brief Review of Claimed Invention

The Applicant believes that it will be helpful to briefly review the invention recited in claims 35 and 46. As noted in earlier Responses, the aspect of the invention recited in claim 35 is most clearly illustrated in Figures 44 and 45 and described in paragraphs [0088] through [0091] of the instant application. As recited in claim 35, the claimed invention is “a surgical device for repairing cartilage tissue at a defect site in a patient,” and includes “a biocompatible anchor shaped to sit within tissue at the defect site and retain a section of cartilage replacement material in the defect site.” With reference to Figures 44 and 45, one

“anchor” according to an aspect of the invention is identified by reference number 5 and the “cartilage replacement material” by the cartilage flap having reference number 4. The claimed device also includes “a biocompatible flexible member,” for example, a suture, which is identified with flexible member 6 in Figures 44 and 45. As claimed, this “flexible member” “travers[es] through said section of cartilage replacement material multiple times.” In Figures 44 and 45, flexible member 6 is shown passing through the replacement material 4 “multiple times.” In addition, the claimed flexible member is “configured to attach to said section of cartilage replacement material at an attachment point.” As shown in Figures 44 and 45, the first end of flexible member 6 is attached to replacement material 4 at attachment point 14 and the second end of flexible member 6 threads through the loop of anchor 5 several times. The claimed flexible member “thread[s] through said anchor at least twice to form at least two pulley mechanisms.” As also shown in Figures 44 and 45, the second end of flexible member 6 threads through the loop of anchor 5 to form these “pulley mechanisms.” The invention recited in claim 35 further includes “a sliding device about said flexible member.” As shown in Figures 44 and 45, this “sliding device” 13 (for example, a slidable knot) is mounted about loop 25 of flexible member 6.

According to the invention recited in claim 35, with the construction describe above, “when in use, the at least two pulley mechanisms are actuated to translate the sliding device distally along said flexible member.” This aspect of the invention is illustrated in the sequence of Figures 44 and 45, wherein, as a surgeon pulls on loop 25, since the flexible member 6 is fixed at attachment point 14 and engages the “pulley mechanism” about anchor 5, the sliding device, or slidable knot, 13 is drawn along loop 25 from a proximal position as shown in Figure 44 to a distal position shown in Figure 45. Accordingly, as recited in claim 35, the slidable device 13 translates along loop 25 of flexible member 6 “to a position proximate said section of cartilage replacement material to locate and retain said section of cartilage replacement material in the defect site.” This positioning and retention of material 4 by slidable device 13 is clearly shown in Figure 45 as slidable device 13 retaining material 4 in the defect site.

The Applicant submits that with this understanding of the claimed invention, the distinctions of the claimed invention from the cited art will be readily apparent.

IB Review of Teachings of Hayhurst

With respect to the rejections of claims 35 and 46, the Patent Office first relies on the teachings of Hayhurst in support of its rejection; in particular, the Patent Office refers to Figures 17 and 19 of Hayhurst. Though the Applicant agrees with the Patent Office that Hayhurst discloses a cartilage tissue replacement material 98, 99; an anchor 80, 110; and a flexible member 82, 120, contrary to the Patent Office's position, the Applicant respectfully submits that Hayhurst fails to teach the claimed invention, that is, in addition to the failures to teach identified by the Patent Office.

First, Hayhurst does not disclose a flexible member "having a first end configured to attach to said section of cartilage replacement material," as recited in claims 35 and 46.

The Applicant reiterates its earlier position that, contrary to the position of the Patent Office, "retainer 68, 69" of Hayhurst does not provide an attachment point to the "cartilage replacement material." In its comments under the heading "Response to Argument," the Patent Office states,

The examiner affirms the rejection as the attachment point is considered the place where the flexible member is connected to the cartilage replacement material.

Retainer 68 describes the location of the flexible member's attachment point as the portion where it attaches to the inside of the cartilage replacement material in the implanted state. [Office Action, page 2, paragraph number 2.]

However, according to the claimed invention, the flexible member is "adapted to be attached" to the cartilage material, not simply ambiguously "connected" to the cartilage material as stated by the Patent Office. The Applicant submits that nowhere in Hayhurst is it disclosed or suggested that the Hayhurst suture 82 is "attached" to material 98. In fact, if suture 82 of Hayhurst were attached or some how fixed to material 98, the device of Hayhurst would not operate as intended.

As described in Merriam-Webster's online dictionary, in the context of the claimed invention, *attach* means,

attach, transitive verb, **4** : to make fast (as by tying or gluing)

[Source: <http://www.merriam-webster.com/dictionary/attached>].

Merriam-Webster also provides the following definition of "fast,"

fast, *adverb* **1** : in a firm or fixed manner <stuck fast>

This meaning of "attached" as "made fast," "made firm," or "made fixed" as used in claim 35 is consistent with this dictionary definition.

However, as described at 8:1-17 of Hayhurst,

The retainer 68 (or retainer 69) may be used in conjunction with the anchor member 50 by inserting the free end 57 of the suture through the retainer at the intersection of the slits 70 after the hollow needle and hollow tube have been withdrawn from around the suture. When the suture 52 is inserted through the retainer 68, the flaps 71 that are defined between adjacent slits 70 are resiliently deformed toward the direction of movement of the suture therethrough. Thereafter, the flaps wedge against the suture 52 and resist withdrawal of the suture through the slits. By applying tension to the suture 52 (see FIGS. 13 and 14) and urging the retainer 68 along the suture to the surface of cartilage 76 from which the suture extends, the retainer may be used to maintain tension in the suture, thereby holding a loose piece of cartilage 76 against the stable piece of cartilage 78 from which the loose piece of cartilage 76 had been torn or fractured. [Hayhurst 8:1-17, emphasis added.]

Clearly, the suture 52 of Hayhurst is not "attached" or "made fast" to cartilage 76 or 98 or 99, nor is suture 52 "attached" or "made fast" to retainer 68. In contrast, as described in the passage above, retainer 68 or 98 of Hayhurst is "wedge[d] against the suture" and "resist[s] withdrawal of the suture," whereby the application of tension to the suture "urg[es] the retainer along the suture." [Emphasis added.] This is how the Hayhurst device works: the retainer 68 is "urged" along suture 52 while maintaining tension in the suture 52. Clearly,

retainer 68 of Hayhurst is not fixed to suture 52, nor *can it be fixed* to suture 52. Accordingly, the Applicant submits that suture 52 is not “attached” or “made fixed” to retainer 68 or cartilage 78 of Hayhurst. Thus, even when combined with Fallin the inventions recited in claims 35 and 46 do not ensue.

Moreover, since the suture 82 of Hayhurst must move relative to the retainer 68 to provide the desired function of the Hayhurst invention, should the suture 82 be “attached” or “made fast” to retainer 68 or cartilage material 76 or 98 or 99, as in the claimed invention, the Hayhurst invention would not work as intended. For example, if the suture 82 were fixed to retainer 68 or to cartilage material 98, the Hayhurst retainer 68 could not be “urg[ed] along the suture” as required by Hayhurst.

For these reasons alone, the Applicant submits that these rejections of claims 35 and 46 are untenable and the Applicant requests that these rejections be reconsidered and withdrawn. However, further distinctions from Hayhurst and Fallin exist.

In addition, with respect to the rejection of claim 35, contrary to the statements made by the Patent Office, Hayhurst also fails to teach that the flexible member “travers[es] through said section of cartilage replacement material multiple times” as recited in claim 35. In support of its rejection, in the first line of page 4 of the Action, the Patent Office cites lines 18-21 in column 10 of Hayhurst for a disclosure of a flexible member traversing a cartilage material multiple times. As best as the Applicant can determine, with reference to Figure 19 of Hayhurst, the cited passage is:

Further, having two suture segments 120 available for securing the tissue to the bone is often desirable.

As described in the paragraph including the above passage, and as shown in Figure 19, suture 118 extends through anchor 110 whereby suture segments 120 emerge from anchor 110. However, contrary to the claimed invention, the Applicant respectfully submits that this passage does not disclose that suture 118 “travers[es] through” a cartilage replacement material “multiple times.” There is no description in this or the adjoining passages that suture 118 traverses a material multiple times. In fact, in the sentences following this passage,

Hayhurst discloses that such an anchor arrangement as shown in Figure 19 can be used to “permit[] each segment [120] of one anchor member [110] to be tied to a corresponding segment [120] of an adjacent anchor member [110]”, suggesting that each segment may traverse a material once and only once, for example, as shown in Figure 18.

Again, the Applicant submits that Hayhurst does not disclose the invention recited in claim 35, even with the teachings of Fallin. The Applicant requests that this rejection be reconsidered and withdrawn.

The Patent Office accurately states that Hayhurst fails to teach flexible member “adapted to thread through said anchor at least twice to form at least two pulley mechanisms” and relies on Fallin to provide these teachings.

However, first, Fallin fails to provide the teachings missing from Hayhurst as describe above. Specifically, (1) Fallin fails to teach a suture “attached” or “made fast” to cartilage, and (2) Fallin fails to teach that the flexible member traverse the cartilage replacement multiple times. Based upon these failures of Hayhurst and Fallin, the Applicant respectfully submits that these rejections of claims 35 and 46 as obvious in view of Hayhurst and Fallin are untenable and requests that they be reconsidered and withdrawn.

Though these distinctions should be sufficient to overcome these rejections, again, further distinctions exist between the claimed inventions and Hayhurst in Fallin.

In support of its rejection, the Patent Office combines the teachings of Hayhurst with the disparate teachings of Fallin. Though both reference are related to the field of medical devices, the relationship between the two devices ends there. As described above, Hayhurst discloses a tissue anchoring system using sutures to retain the tissue to an anchor embedded in bone beneath the tissue. In contrast, as shown most clearly in Figures 10-15, Fallin discloses a system for repairing tissue by passing an “anchor” 56 through the tissue and using the “anchor” 56 to retain the suture against the free surface of the tissue. Moreover, the Applicant submits that, though Fallin describes the structure as “an anchor” 56, structure 56 functions as “a retainer,” not as an anchor as in the claimed inventions.

As recited in claim 35, the invention includes “a biocompatible anchor shaped to sit within tissue at the defect site” [Emphasis added.] As clearly shown in Figures 10-15 of Fallin, retainer 56, 58 is not “shaped to sit within tissue” but is shaped to pass through and retain a suture against tissue. Accordingly, the Fallin device does not function in the same way as the claimed invention and therefore would not be of use to one of skill in the art when attempting to address the deficiencies of Hayhurst and related art.

Moreover, contrary to the claimed invention and contrary to the teachings of Hayhurst, Fallin does not retain any “replacement material in defect site” as claimed. Under the heading, “Response to Arguments,” the Patent Office supports this rejection by stating,

The examiner affirms the rejection as Fallin et al. disclosed a two suture anchor system (suture 60 and line 94) that uses two pulley mechanisms formed by passageways 68A-68C that are used to tension an anchor to a defect site. By pulling on suture 60, the anchors move closer to each other while locating and retaining a piece of cartilage (paragraph 65).

First, the Applicant is unclear what the reference is to “paragraph 65.” The Applicant assumes that the Patent Office is referring to paragraph 0065 of published application 20040002734, and not US patent 6,972,027.

Second, Fallin does not disclose “locating and retaining a piece of cartilage” as in the present invention. As clearly disclosed in Figures 10-15, the Fallin device does not retain replacement cartilage material, but, as described at 8:30-32, the Fallin device “holds tear 100 [in meniscus 98] sufficiently tightly closed to ensuring [sic] healing thereat.” No replacement material is handled by Fallin. Fallin does not function in the same way or provide the desired results as the claimed invention, or of the device of Hayhurst. Based upon these distinctions alone, this rejection is inappropriate. The Applicant respectfully requests that these rejections of claims 35 and 46 as obvious in view of Hayhurst and Fallin be reconsidered and withdrawn. However, more stark distinctions from the claimed invention are present in Fallin.

Neither Hayhurst nor Fallin disclose “a sliding device” as recited in claims 35 and 46.

In the passages on page 4 of the Action, the Patent Office associates the loop 88 of Fallin with the claimed slidable device. Specifically, the Patent Office states,

The opposite end 84 (figure 7) of said flexible member is looped around said member 60 to form a sliding device 88 (figure 7) for adjusting said distance between attachment point 58 (figure 7) and said anchor [56?].

However, contrary to the claimed invention, as described above, loop 88 of Fallin is not a “sliding device,” nor does loop 88 provide any type of sliding along a suture to retain a replacement material. In contrast, according to the claimed invention, for example, as shown in Figures 44 and 45 of the instant application, suture 24 is formed into a sliding device 13, for example, a knot, which translates along proximal loop 25 to retain material 4 in defect site 3.

In comparison of the features of Fallin with the claimed invention, the only structure of Fallin that may “slide” along a suture is anchor 56. However, according to aspects of the invention, the claimed anchor is a distinct structure from the claimed sliding device. The anchor 56 of Fallin cannot correspond to both the claimed anchor and the claimed sliding device.

Again, for all these reasons, even when combined, Hayhurst and Fallin do not provide the disclosed invention. The Applicant submits that claims 35 and 46 are not obvious in view of Hayhurst and Fallin. The Applicant respectfully requests that these rejections of claims 35 and 46 as obvious in view of Hayhurst and Fallin be reconsidered and withdrawn.

IC The Dependent Claims

With respect to the rejections of dependent claims 36, 38, 43, 45, 47, 49, 54, and 55, the Applicant submits that these claims are not obvious in view of Hayhurst and Fallin for the same reasons that claims 35 and 46, from which they depend, are not obvious. In addition, aspects of the dependent claims are not disclosed or suggested by Hayhurst and Fallin. For example, with respect to claim 36, neither Hayhurst, nor Fallin teach or suggest that a

“flexible member comprise[] a first end and a second end, wherein the first end is positioned at said attachment point [of the cartilage] and the second end compris[e] the sliding device” as recited in this claim.

With respect to claim 38, neither Hayhurst, nor Fallin teach or suggest that a “sliding device comprise[] a slipknot fashioned about said flexible member which, when tensioned about said flexible member, retains said section of cartilage replacement material in the defect site” as recited in this claim.

The Applicant respectfully requests that these rejections be reconsidered and withdrawn.

II Response to Obviousness Rejection Based upon Hayhurst and Fallin and others

In paragraph 9 on page 5 of the Action, the Patent Office rejected claims 39-41 and 51-53 pursuant to 35 U.S.C. §103(a) as obvious in view of the combined teachings of Hayhurst and Fallin and U.S. Patent Application Publication 2005/0113937 of Binette, et al. [herein “Binette”]. In paragraph 10 on page 5 of the Action, the Patent Office rejected claim 42 pursuant to 35 U.S.C. §103(a) as obvious in view of the combined teachings of Hayhurst and Fallin and U.S. Patent Application Publication 2004/0267314 of Wolf, et al. [herein “Wolf”]. The Applicant respectfully submits that these rejections are inappropriate and requests that these rejections be reconsidered and withdrawn based upon the following comments and observations.

First, the Applicant submits that these claims are patentably distinct from Hayhurst, Fallin, and Binette or Wolf for the same reasons that their parent claims are patentably distinct from Hayhurst and Fallin. Based upon this distinction alone, the Applicant requests that these rejections be reconsidered and withdrawn.

Second, the Applicant submits that neither Binette, nor Wolf address the deficiencies of Hayhurst and Fallin. Specifically, (1) Binette and Wolf fail to teach a suture “attached” or “made fast” to cartilage, and (2) Binette and Wolf fail to teach that the flexible member

U.S. Serial No.: 10/598,223
U.S. Filing Date: August 22, 2006
RCE and Response dated December 14, 2009
Attorney Docket No.: 3124.006A

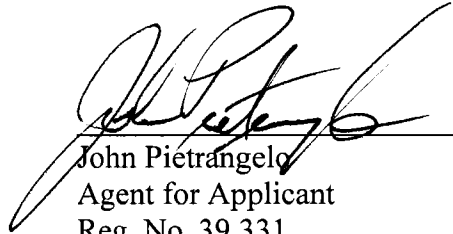
traverse the cartilage replacement multiple times that are missing from Hayhurst and Fallin. Based upon these distinctions, the Applicant requests that these rejections be reconsidered and withdrawn.

CONCLUSION

The Applicant believes that the above Amendment and Remarks place the application in allowable form. An early and favorable action on the merits of the application is requested.

If a telephone conference would be of assistance in advancing prosecution of the subject application, the Applicant's undersigned Agent invites the Examiner to telephone him at the number provided.

Respectfully submitted,



John Pietrangelo
Agent for Applicant
Reg. No. 39,331

Dated: December 14, 2009

HESLIN ROTHENBERG FARLEY & MESITI P.C.

5 Columbia Circle
Albany, New York 12203-5160
Telephone: (518) 452-5600
Facsimile: (518) 452-5579